UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of: **Pfizer Pharmaceuticals LLC** PR Road Km. 8.2 Barceloneta, Puerto Rico **Respondent** In a proceeding under Section 113(a) of the Clean Air Act, 42 U.S.C. § 7413(a)	**COMPLIANCE ORDER** CAA-02-2010-1020

Statutory Authority

The United States Environmental Protection Agency (EPA) Region 2, Director of the Caribbean Environmental Protection Division (CEPD) issues this COMPLIANCE ORDER (Order), pursuant to the Clean Air Act, 42 U.S.C. § 7401 *et seq.*, (the Act or CAA), at 42 U.S.C. § 7413 (a), Section 113(a), to Pfizer Global Manufacturing (Pfizer or Respondent), the owner and/or operator of a pharmaceutical plant located at PR Road 2 kilometer 8.2, Barceloneta, Puerto Rico (the Facility). Section 113(a) of the Act authorizes EPA to issue Compliance Orders requiring persons who operate sources of air pollution to comply with the requirements of the Act and the rules and regulations that EPA promulgated under the Act, including regulations promulgated under Sections 112 and 114, and permits issued pursuant to a State title V program adopted and approved pursuant to title V of the Act. The authority to find violations and issue this Order has been delegated to the Director of the Caribbean Environmental Protection Division (CEPD) from the EPA Administrator through the Regional Administrator.

Section 112 of the Act requires the Administrator to publish a list of hazardous air pollutants (HAPs), a list of categories and subcategories of major and area sources of listed HAPs, and to promulgate regulations establishing emission standards, referred to as National Emissions Standards for Hazardous Air Pollutants (NESHAPs) for each category or subcategory of major and area sources of HAPs.

Section 113(a) of the Act authorizes EPA to issue compliance orders requiring persons who operate sources of air pollution to comply with the requirements of the Act and the rules and regulations that EPA promulgated under the Act, including regulations promulgated under Sections 112 and 114, and permits issued pursuant to a State title V program adopted and approved pursuant to title V of the Act.

Section 114(a)(1) of the Act authorizes EPA to require owners and operators of emission sources to provide specific information regarding their facilities, establish and maintain records, make reports, sample emission points, and to install, use and maintain such monitoring equipment or methods in order to determine whether any person is in violation of the Act.

Statutory, Regulatory, and Permitting Background

1. Section 112(a)(1) of the Act defines a "major source" as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit ten (10) tons per year (tpy) or more of any HAP or twenty-five (25) tpy or more of any combination of HAPs.

2. Section 112(a)(1) of the Act defines an "area source" as any stationary source of hazardous air pollutants that is not a major source.

3. Section 112(b)(1) of the Act lists the applicable HAPs.

4. Section 112(c) of the Act requires the Administrator to publish a list of categories or subcategories of major and area sources of listed HAPs.

5. Section 112(d) of the Act requires the Administrator to promulgate regulations establishing NESHAPs for each category or subcategory of major and area sources of listed HAPs.

6. Section 112(d)(3) of the Act, as amended November 15,1990, requires the Administrator to develop standards, for categories or subcategories, that are as stringent as the average control efficiency or the best controlled twelve percent of similar sources excluding sources that have achieved the lowest achievable emission rate (LAER) within eighteen months prior to proposal or thirty months prior to promulgation of the standard. These NESHAPs are known as "maximum available control technology" (MACT) standards.[1]

7. Section 302(e) of the Act defines the term "person" as an individual, corporation, partnership, association, state municipality, political subdivision of a state, and an agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

8. Section 501(2) of the Act provides that the term "major source" means any stationary source (or group of stationary sources located within a contiguous area and under common control) that is a major source as defined in Section 112 of the Act, and Section 302 of the Act or part D of subchapter I of the Act.

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1 Prior to the 1990 amendments to the Act, standards promulgated pursuant to Section 112 of the Act considered quantified analysis of the risk to human health and did not use this formula. These NESHAPs are promulgated at 40 C.F.R. Part 61.

9. Section 502(a) of the Act provides that after the effective date of any permit program approved or promulgated pursuant to title V of the Act, it shall be unlawful for any person to violate any requirement of a permit issued under title V of the Act or to operate a title V affected source, including a major source or any other source (including an area source) subject to standards or regulations under, among other things, Section 112 of the Act, except in compliance with a permit issued by a permitting authority under title V of the Act.

10. Section 502(b) of the Act requires EPA to promulgate regulations establishing the minimum elements of a permit program to be administered by any air pollution control agency and set forth the procedures by which EPA will approve, oversee, and withdraw approval of state operating permit programs.

11. Section 502(d)(1) of the Act requires each state to develop and submit to the Administrator a permit program meeting the requirements of title V of the Act.

12. 40 C.F.R. Part 70, promulgated pursuant to title V of the Act, among other things, sets forth corresponding minimum requirements for state operating permit programs.

13. 40 C.F.R. Part 71, sets forth the comprehensive federal air quality operating permit program consistent with the requirements of title V of the Act, and defines the requirements and the corresponding procedures by which EPA will issue title V operating permits.

14. 40 C.F.R. Part 70, Appendix A, provides information on the approval status of state and local operating permit programs. The Puerto Rico Environmental Quality Board ("PREQB") submitted to EPA the title V operating permit program on

November 15, 1993, with supplements on March 22 and April 11, 1994, and revised on September 29, 1995. The EPA granted approval of the Puerto Rico title V Operating Permit Program on February 26, 1996, 61 Fed. Reg. 7073 (February 26, 1996).

15. Rule 211 of the of the Puerto Rico Regulation of the Control of Atmospheric Air Pollution (RCAP), approved into the PR SIP, was created for the purpose of determining applicability of RCAP Part VI (PR-EQB's title V rules) as a federally enforceable means to limit the potential to emit criteria and hazardous air pollutants from stationary sources, and to establish requirements for all sources that maintain emissions below the Part VI major source levels.

16. Rule 211 of the RCAP applies to any stationary source which would, if it did not comply with the limitations set forth in Rule 211, have the potential to emit air contaminants equal to or in excess of the Part VI major source thresholds, and any stationary source that maintains its emission levels below the Part VI major source thresholds and selects to be covered by this Rule, and to any stationary source which meets one of the conditions specified in the Rule.

17. Section 503(a) of the Act provides that any source specified in Section 502(a) of the Act shall become subject to a permit program and shall be required to have a permit to operate.

18. On March 16, 1994, pursuant to Sections 112 and 114 of the Act, EPA promulgated 40 C.F.R. Part 63, Subpart A, §§ 63.1 – 63.16 (General MACT).

19. Pursuant to 40 C.F.R. § 63.1(a)(4), each relevant standard in 40 C.F.R. Part 63 must identify explicitly whether each provision in the General MACT is or is not included in such relevant standard.

20. Pursuant to 40 C.F.R. § 63.1(b), the provisions of 40 C.F.R. Part 63 apply to the owner or operator of any stationary source that (i) emits or has the potential to emit any HAP listed in or pursuant to Section 112(b) of the Act, and (ii) is subject to any standard, limitation, prohibition, or other federally enforceable requirement established pursuant to Part 63.

21. Methylene chloride ($MeCl_2$) is listed in 40 C.F.R. Part 63 as a HAP.

22. Pursuant to 40 C.F.R. § 63.1(c), if a relevant standard has been established under Part 63, the owner or operator of an affected source must comply with the provisions of that standard and of the General MACT, as provided in 40 C.F.R. § 63.1(a)(4).

23. 40 C.F.R. § 63.2 defines "affected source," for the purposes of Part 63, as the stationary sources, the group of stationary sources, or the portion of a stationary source that is regulated by a relevant standard or other requirement established pursuant to Section 112 of the Act.

24. 40 C.F.R. § 63.2 defines "existing source" as any affected source that is not a new source.

25. 40 C.F.R. § 63.2 defines "owner or operator" as any person who owns, leases, operates, controls, or supervises a stationary source.

26. Pursuant to 40 C.F.R. § 63.6(c), after the effective date of a relevant standard established under 40 C.F.R. Part 63, the owner/operator of an existing source must comply with such standard by the compliance date established by the Administrator in the applicable Subpart(s) of 40 C.F.R. Part 63.

27. On October 18, 1983, EPA promulgated the Standard of Performance for

Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry for which Construction, Reconstruction, or Modification Commenced After January 5, 1981, and on or Before November 7, 2006, 40 C.F.R. §§ 60.480 - 60.489 (48 Fed. Reg. 48335).

28. Pursuant to 40 C.F.R. § 60.480(a)(1), the provisions of Subpart VV apply to affected facilities in the synthetic organic chemicals manufacturing industry.

29. Pursuant to 40 C.F.R. § 60.480(a)(2), the group of all equipment (defined in § 60.481) within a process unit is an affected facility.

30. Pursuant to 40 C.F.R. § 60.480(b), any affected facility under § 60.480(a) that commences construction, reconstruction, or modification after January 5, 1981, and on or before November 7, 2006, shall be subject to the requirements of Subpart VV.

31. On April 22, 1994, pursuant to Sections 112 and 114 of the Act, EPA promulgated 40 C.F.R. Part 63, Subpart H, §§ 63.160 – 63.183, the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks (HON MACT), 59 Fed. Reg. 19,568 (April 22, 1994).

32. Pursuant to 40 C.F.R. § 63.160(a), the provisions of Subpart H apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, and control devices or closed vent systems required by Subpart H that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a source subject to the provisions of a specific subpart in 40 C.F.R. Part 63 that references Subpart H.

33. Pursuant to 40 C.F.R. § 63.160(b)(1), after the compliance date for a

process unit to which Subpart H and the provisions of 40 C.F.R. Part 60 apply, the unit will be required to comply only with the provisions of Subpart H.

34. Pursuant to 40 C.F.R. § 63.160(c), if a facility has equipment to which Subpart H does not apply, but which is subject to a standard identified in § 63.160(c)(1), (c)(2), or (c)(3), the owner or operator may elect to apply Subpart H to all such equipment in the process unit. If the owner or operator elects this method of compliance, all VOC in such equipment shall be considered, for purposes of applicability and compliance with Subpart H, as if it were organic HAP. Compliance with the provisions of Subpart H, in the manner described in this paragraph, shall be deemed to constitute compliance with the standards identified in § 63.160(c)(1), (c)(2), or (c)(3): (1) 40 C.F.R. Part 60, Subpart VV, GGG, or KKK; (2) 40 C.F.R. Part 61, Subpart F or J; (3) 40 C.F.R. Part 264, Subpart BB; or (4) 40 C.F.R. Part 265, Subpart BB.

35. Pursuant to 40 C.F.R. § 63.162(a), compliance with Subpart H will be determined by review of the records required by §63.181 and the reports required by § 63.182 of Subpart H, review of performance test results, and by inspections.

36. Pursuant to 40 C.F.R § 63.163(b)(1), the owner or operator of a process unit subject to Subpart H shall monitor each pump monthly to detect leaks by the method specified in § 63.180(b) of Subpart H and shall comply with the requirements of § 63.163(a) through (d), except as provided in § 63.162(b) of Subpart H and § 63.163(e)-(j).

37. Pursuant to 40 C.F.R. § 63.163(c)(1), when a leak at the valves is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in § 63.163(c)(3) or § 63.171 of Subpart H.

38. Pursuant to 40 C.F.R. § 63.163(c)(2), a first attempt at repair for valves that are either in gas service or in light liquid service shall be made no later than 5 calendar days after the leak is detected.

39. Pursuant to 40 C.F.R § 63.167(a)(1), each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.162(b) of Subpart H and paragraphs (d) and (e) of § 63.167.

40. Pursuant to 40 C.F.R § 63.167(a)(1), each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.162(b) and § 63.167(d) and (e) of Subpart H.

41. Pursuant to 40 C.F.R § 63.167(a)(2), the cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.

42. Pursuant to 40 C.F.R § 63.168(b), the owner or operator of a source subject to Subpart H shall monitor all valves, except as provided in § 63.162(b) of Subpart H and paragraphs (h) and (i) of § 63.168, at the intervals specified in § 63.168(c) and (d) and shall comply with all other provisions of § 63.168, except as provided in § 63.171, § 63.177, § 63.178, and § 63.179 of Subpart H.

43. Pursuant to 40 C.F.R § 63.168(c), in Phases I and II, each valve shall be monitored quarterly.

44. Pursuant to 40 C.F.R. § 63.168(f)(1), when a leak at a valve that is in light liquid service is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in § 63.171 of Subpart H.

45. Pursuant to 40 C.F.R. § 63.168(f)(2), a first attempt at repair for each pump that is in light liquid service shall be made no later than 5 calendar days after the leak is detected.

46. Pursuant to 40 C.F.R. § 63.173(c)(1), when a leak at an agitator is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in § 63.171 of Subpart H.

47. Pursuant to 40 C.F.R. § 63.173(c)(2), a first attempt at repair for agitators shall be made no later than 5 calendar days after the leak is detected.

48. Pursuant to 40 C.F.R § 63.173(a)(1), each agitator shall be monitored monthly to detect leaks by the methods specified in § 63.180(b) of Subpart H, except as provided in § 63.162(b) of Subpart H.

49. Pursuant to 40 C.F.R § 63.173(c)(1), when a leak in an agitator is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in § 63.171 of Subpart H.

50. Pursuant to 40 C.F.R § 63.173(c)(2), a first attempt at repair to an agitator, shall be made no later than 5 calendar days after each leak is detected.

51. Pursuant to 40 C.F.R § 63.174(a), the owner or operator of a process unit subject to shall monitor all connectors in gas/vapor and light liquid service, except as provided in § 63.162(b) of Subpart H, and in § 63.174(f) through (h), at the intervals specified in § 63.174(b).

52. Pursuant to 40 C.F.R § 63.174(b)(3)(i), all connectors in gas/vapor and light liquid service shall be monitored once per year (i.e., 12-month period), if the percentage of leaking connectors in the process unit was 0.5 percent or greater during

the last required annual or biennial monitoring period.

53. Pursuant to 40 C.F.R. § 63.174(d), when a leak at a connector in gas/vapor and light liquid service is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in § 63.174(g) and in § 63.171 of Subpart H. A first attempt at repair shall be made no later than 5 calendar days after the leak is detected.

54. Pursuant to 40 C.F.R § 63.180(a), each owner or operator subject to the provisions of Subpart H shall comply with the test methods and procedures requirements provided in § 63.180.

55. Pursuant to 40 C.F.R § 63.180(b)(1), monitoring, as required by Subpart H shall comply with Method 21 of 40 C.F.R. Part 60, Appendix A (Method 21).[2]

56. Pursuant to 40 C.F.R § 63.180(b)(2)(i), except as provided for in § 63.180(b)(2)(ii), the detection instrument shall meet the performance criteria of Method 21, except the instrument response factor criteria in Section 3.1.2(a) of Method 21 shall be for the average composition of the process fluid not each individual VOC in the stream. For process streams that contain nitrogen, water, air, or other inerts which are not organic HAPs or VOCs, the average stream response factor may be calculated on an inert-free basis. The response factor may be determined at any concentration for which monitoring for leaks will be conducted.

57. Pursuant to 40 C.F.R. § 63.180(b)(3), the instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21.

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2 8.1.3 The Response. The response time test is required before placing the instrument into service. If a modification to the sample pumping system or flow configuration is made that would change the response time, a new test is required before further use.

58. Pursuant to 40 C.F.R § 63.181(a), an owner or operator of more than one process unit subject to the provisions of Subpart H may comply with the recordkeeping requirements for these process units in one recordkeeping system if the system identifies each record by process unit and the program being implemented (e.g., quarterly monitoring, quality improvement) for each type of equipment. All records and information required by § 63.181 shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site.

59. Pursuant to 40 C.F.R. § 63.182(d), the owner or operator of a source subject to Subpart H shall submit Periodic Reports.

60. Pursuant to 40 C.F.R. § 63.182(d)(xiv), the periodic reports shall contain the results of all monitoring to show compliance with §§ 63.164(i), 63.165(a), and 63.172(f) of Subpart H conducted within the semiannual reporting period.

Findings of Fact

61. On February 3, 2004, PREQB issued the State Operating Permit # PFE-09-0203-0146-I-II-O to Respondent. The State Operating Permit expired on February 3, 2009, and a renewal application was submitted by Respondent on December 2008, identified as PFE-09-1208-0608-I-II-O. The new permit has not been issued yet.

62. The Facility's State Operating Permit # PFE-09-0203-0146-I-II-O indicates that the Facility's total annual HAPs emissions do not exceed 10 tpy of any HAP or 25 tpy of combined HAPs.

63. The Facility's State Operating Permit indicates that the Facility must comply with 40 C.F.R. Part 63, Subpart H (the HON MACT).

64. On March 4 and 5, 2010, EPA and PREQB conducted a HON MACT Leak Detection and Repair (LDAR) inspection (EPA Inspection) at the Facility.

65. During the EPA Inspection, Mr. Santos (Respondent's Environmental Supervisor), Mr. Arroyo and Ms. Soto (Respondent's LDAR technicians) accompanied EPA.

66. During the EPA Inspection, Mr. Santos informed EPA that the Facility is subject to the HON MACT due to the use of methylene chloride in several of its manufacturing batch processes.

67. During the EPA Inspection, Mr. Santos informed EPA that methylene chloride is the only HAP used at the Facility that is regulated under the HON MACT.

68. During the EPA Inspection, Mr. Santos informed EPA that the Facility is a synthetic minor source, since it limited its emissions to below the 10/25 tpy threshold.

69. During the EPA inspection, Mr. Santos also informed the EPA that he supervises the implementation of the LDAR Program.

70. During the EPA Inspection, Mr. Santos and Mr. Arroyo informed EPA that all first attempts at repair for all affected components are made by Mr. Arroyo.

71. During the EPA Inspection, Mr. Santos informed EPA that the Facility was having difficulties retrieving its historic LDAR monitoring data. Raw data requested by EPA was not able to be extracted from Respondent's database.

72. During the EPA Inspection, leak records, work orders and leak repairs from 2005 through 2009 were reviewed.

73. During the EPA Inspection, EPA observed a routine instrument calibration conducted by Mr. Arroyo and confirmed that Respondent's technician performed a bump calibration or a calibration drift test. However, 40 C.F.R § 63.180(b)(3) and the procedures specified in Method 21, require the Facility to make a daily calibration instead of a bump calibration or a calibration drift test.

74. During the EPA Inspection, EPA also confirmed with Mr. Santos and Mr. Arroyo that Respondent has never conducted a response time test before placing the instrument into service.

75. During the EPA Inspection, Mr. Santos and Mr. Arroyo informed EPA that Respondent owns and maintains 3 Total Volatile Analyzers, model TVA 1000s, which are the instruments used by Respondent to conduct leak detection monitoring at the Facility.

76. During the EPA Inspection, Mr. Arroyo informed EPA that the Facility uses the following calibration gases: zero air, 550 parts per million (ppm) methane (CH_4), 1,000 ppm CH_4, and 9,500 ppm CH_4.

77. During the EPA Inspection, EPA performed monitoring (EPA Monitoring Review) side by side with Mr. Arroyo and Ms. Soto, at 341 components subject to the Facility's HON MACT LDAR Program.

78. During the EPA Monitoring Review, EPA found four (4) leaks located at flange TS-HV-111B04-001, plug NT-001, plug TS-HV-100AB04-003 and flange SR-P-01C01-002 and 2 visual leaks at flange G-XV-02S85-001 and valve G-HV-04S86-000.

79. During EPA Monitoring Review, EPA also found and took pictures of three

(3) open-ended lines (OELs) identified by EPA as S-HV-14S97, G-FL-012S76-003 and SR-P-01C01-002.

80. On March 17, 2010, Respondent sent a letter signed by Mr. Eduardo Cordero, Environmental, Health and Safety (EHS) Director/Team Leader, to Ms. Reshma Punwasie, EPA's LDAR Lead Auditor. The letter states that: (1) all leaks found during the EPA Inspection were repaired and corrected; (2) OELs were immediately capped during the EPA Inspection;[3] (3) that Respondent has implemented the procedures as required in EPA Method 21 to include the response time determination; (4) that Respondent has implemented the practice to conduct daily calibrations during all LDAR monitoring activities.

81. EPA conducted a review of the information obtained during the EPA Inspection, and subsequent to it, as well as the one offered as part of Respondent's March 17, 2010 letter.

Conclusions of Law

82. Paragraphs 1-81 are realleged and incorporated herein by reference.

83. From the Findings of Fact set forth above, EPA finds that Respondent is a person within the meaning of Section 302(e) of the Act.

84. From the Findings of Fact set forth above, EPA finds that the Facility is an area source, within the meaning of Section 112 of the Act.

3. During the EPA Inspection, EPA found 3 OELs that were not capped, identified in EPA's Inspection Report by EPA as: S-HV-14S97, G-FL-012S76-003 and G-HV-07S84-002. However, Respondent's March 10, 2010 letter identifies the OELs as: S-HV-14S97, G-FL-012S76-003 and TS-HV-111B04. The discrepancy between these last two identification tags (EPA understands it is G-HV-07S84-002, and Respondent identifies it as TS-HV-111B04) needs to be clarified in order to assess Respondent's compliance.

85. From the Findings of Fact set forth above, EPA finds that the Facility is an existing source, within the meaning of 40 C.F.R. § 63.2.

86. From the Findings of Fact set forth above, EPA finds that the Facility is an affected source, within the meaning of 40 C.F.R. § 63.2.

87. From the Findings of Fact set forth above, EPA finds that Respondent is an owner or operator of the Facility, within the meaning of 40 C.F.R. § 63.2.

88. From the Findings of Fact set forth above, EPA finds that the Facility emits or has equipment containing or contacting one or more of the HAPs listed in Section 112(b) of the Act.

89. From the Findings of Fact set forth above, EPA finds that Respondent operates a synthetic organic chemical manufacturing process facility subject to the General MACT and the HON MACT.

90. From the Findings of Fact set forth above, EPA finds that Respondent is subject to the HON MACT as of April 22, 1994.

91. From the Findings of Fact set forth above, EPA finds that the Facility is required to implement and comply with the HON MACT, as specified in 40 C.F.R. Part 63, Subpart H.

92. From the Findings of Fact set forth above, EPA finds that Respondent failed to develop and implement the Facility's HON MACT LDAR Program and therefore violated the HON MACT.

93. From the Findings of Fact set forth above, EPA finds that Respondent failed to cap three (3) OELs, in violation of 40 C.F.R § 63.167(a)(1).

94. From the Findings of Fact set forth above, EPA finds that Respondent

failed to conduct response time tests , in violation of 40 C.F.R § 63.180(b)(1) and the procedures specified in Method 21.

95. From the Findings of Fact set forth above, EPA finds that Respondent failed to conduct daily calibration in violation of 40 C.F.R § 63.180(b)(3) and the procedures specified in Method 21.

Order

In concurrence with the Findings of Fact and Conclusions of Law above, and in accordance with Section 113(a)(4) of the Act, IT IS DETERMINED AND ORDERED that:

I.

The provisions of this Compliance Order shall apply to Respondent and to its officers, agents, servants, employees, successors and to all persons, firms and corporations acting pursuant to, through or for Respondent.

II.

Upon the effective date of this Order, Respondent shall comply with all applicable monitoring requirements of 40 C.F.R. Part 63, Subpart H. In addition, Respondent shall submit a copy of its amended LDAR Standard Operating Program (SOP) which describes the daily calibrations and response time tests procedures to be followed prior to putting in service its 3 Total Volatile Analyzers, model TVA 1000, as required by EPA Method 21.

III.

Upon the effective date of this Order, Respondent shall comply with all applicable

recordkeeping requirements of 40 C.F.R. Part 63, Subpart H. Including maintaining copies of all the records, since March 5, 2010, showing the daily calibrations and response time tests conducted at each equipment used during leak tests, as required by EPA Method 21

IV.

Within thirty (30) days of the effective date of this Order, Respondent shall submit a detailed report explaining the discrepancies between EPA's findings on March 5, 2010, where EPA identified three (3) the OELs without a cap as: (1) G-FI-012S76, (2) S-HV-14S97 and (3) G-HV and Respondent's March 17, 2010 letter where it reports capping three (3) open-ended lines identified as: (1) G-FI-012S76, (2) S-HV-14S97 and (3) TS-HV-111B04. The report shall also include how Respondent's LDAR SOP was amended to include procedures to ensure that in the future no OEL will be left without a cap.

V.

Upon the effective date of this Order, Respondent shall comply with all applicable monitoring and calibrations requirements listed in 40 C.F.R. Part 63, Subpart H.

VI.

Upon the effective date of this Order, Respondent shall comply with all applicable requirements for open-ended valves or lines listed in 40 C.F.R. Part 63, Subpart H.

Business Confidentiality

Respondent may assert a business confidentiality claim covering part or all of the information this Order requires only to the extent and in the manner described in

40 C.F.R. § 2.203. EPA will disclose information submitted under a confidentiality claim only as provided in 40 C.F.R. Part 2, Subpart B. *See* 41 Fed. Reg. 36,902 (September 1st, 1976). If Respondent does not assert a confidentiality claim, EPA may make the information available to the public without further notice to Respondent.

Enforcement

Section 113(a)(3) of the Act authorizes EPA to take any of the following actions in response to Respondent's violation(s) of the Act:

- issue an administrative penalty order, for penalties up to $25,000 per day pursuant to Section 113(d) of the Act and adjust the maximum penalty provided by the Act up to $27,500 per day for each violation that occurs from January 30, 1997 through March 14, 2004, $32,500 per day for each violation that occurs from March 15, 2004 through January 12, 2009, and $37,500 per day for each violation that occurs after January 12, 2009, in accordance with the Debt Collection Improvement Act, 31 U.S.C. § 3701 *et seq.* (DCIA), and 40 C.F.R. Part 19, promulgated pursuant to DCIA;

and

- bring a civil action pursuant to Section 113(b) of the Act for injunctive relief and/or civil penalties, and in accordance with the DCIA and 40 C.F.R. Part 19, as stated directly above.

Failure to comply with this Order may result in an administrative or civil action for appropriate relief as provided in Section 113 of the Act. EPA retains full authority to enforce the requirements of the Act, for all periods of non-compliance including those

covered in this Order, and nothing in this Order shall be construed to limit that authority. Furthermore, the United States may seek fines and/or imprisonment of any party who knowingly violates the Act or an Order issued pursuant to Section 113 of the Act. Upon conviction, any facility owned by such party may be declared ineligible for federal contracts, grants and loans. Section 306; 40 C.F.R. Part 15; and Executive Order 1738.

Penalty Assessment Criteria

Section 113(e)(1) of the Act states that if a penalty is assessed pursuant to Sections 113 of the Act, the Administrator or the court, as appropriate, shall, in determining the amount of the penalty to be assessed, take into consideration the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violation as established by any credible evidence (including evidence other than the applicable test method), payment by the violator of penalties previously assessed for the same violation, the economic benefit of noncompliance, the seriousness of the violation, and other factors as justice may require.

Section 113(e)(2) of the Act allows the Administrator or the court, as appropriate, to assess a penalty for each day of violation. In accordance with Section 113(e)(2) of the Act, EPA will consider a violation to continue from the date the violation began until the date Respondent establishes that it has achieved continuous compliance. If Respondent proves that there was an intermittent day of compliance or that the violation was not continuous in nature, then EPA will reduce the penalty accordingly.

Effective Date and Opportunity for Conference

Pursuant to Section 113(a)(4) of the Act, Respondent may request a conference with EPA concerning the violation(s) alleged in this Order. This conference will enable Respondent to present evidence bearing on the finding of violation, on the nature of the violation, and on any efforts it may have taken or it proposes to take to achieve compliance. Respondent may arrange to have legal counsel.

Respondent's request for a conference must be confirmed in writing within ten (10) days of receipt of this Order. If the requested conference is held, the Order shall become effective ten (10) days after the conference is held.

If Respondent does not request a meeting within twenty (20) days of receipt of this Order, the Order shall become effective ten (10) days from its receipt. The request for a conference, or other inquiries concerning this Order, should be made in writing to:

Carolina Jordan Garcia
Assistant Regional Counsel
Office of Regional Counsel – CT
U.S. Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
1492 Ponce de Leon Ave. Suite 417
San Juan, Puerto Rico 00907
jordan-garcia.carolina@epa.gov
Tel.: (787) 977-5834
Fax: (787)729-7748

Notwithstanding the effective date of this Order and opportunity for conference, Respondent must comply with all applicable requirements of the Act.

Issued: Sept 29, 2010

Carl-Axel P. Soderberg, Director
Caribbean Environmental Protection Division
U.S. Environmental Protection Agency - Region 2

To: Eduardo Cordero
Director/Team Leader EHS
Pfizer Pharmaceuticals LLC
PO BOX 628
Barceloneta PR 00617

cc: Pedro J. Nieves, Chairman
Puerto Rico Environmental Quality Board

IN THE MATTER OF:

Pfizer Pharmaceuticals LLC
PR Road Km. 8.2
Barceloneta, Puerto Rico 00617

Respondent

In a proceeding under Section 113(a) of the Clean Air Act, 42 U.S.C. §7413(a)

COMPLIANCE ORDER
CAA-02-2010-1020

CERTIFICATE OF SERVICE

I certify that the foregoing Compliance Order was sent to the following person, in the manner specified, on the date below:

Original via Certified Mail Return Receipt:

Eduardo Cordero
Director/Team Leader EHS
Pfizer Pharmaceuticals LLC
P.O. Box 628
Barceloneta, PR 00617

Dated: 7/30/10

Aileen Sanchez ORC-CT